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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,501	11/07/2001	Joseph M. Gabriele	62,453-015	9957

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EXAMINER

PURVIS, SUE A

ART UNIT PAPER NUMBER

1734

DATE MAILED: 09/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/045,501	<b>Applicant(s)</b> GABRIELE, JOSEPH M. <span style="float: right;">KB</span>	
	<b>Examiner</b> Sue A. Purvis	<b>Art Unit</b> 1734	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-28 is/are pending in the application.  
     4a) Of the above claim(s) 20-28 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 15-17 is/are allowed.
- 6) ☒ Claim(s) 1-4, 7-10, 14 and 18 is/are rejected.
- 7) ☒ Claim(s) 5, 6, 11-13 and 19 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                            | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.                                                |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-19, drawn to a method of forming an aseptic enclosure, classified in class 156, subclass 245.
  - II. Claims 20-28, drawn to a bag-like aseptic enclosure, classified in class 604, subclass 408.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process as claimed can be used to make different products.
3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.
4. Because these inventions are distinct for the reasons given above and the search required for Group II is not required for Group I, restriction for examination purposes as indicated is proper.
5. During a telephone conversation with Raymond E. Scott on 16 September 2004 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-19. Affirmation of this election must be made by applicant in replying to this Office action.

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Claims 20-28 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1, 3, 8-10, 14, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rausing (US Patent No. 3,911,640).

Rausing discloses a method for making a package under aseptic conditions which includes heating a thermoformable web, using a thermoforming tool (19, 20) and ending with the resulting bodies (21) being formed. (Figure 1.)

Rausing does not detail clamping the peripheral portion and driving a platen to form the bag-like enclosure, however it is within the purview of the artisan to know that the forming tools (19, 20, 33) clamp the film and form the shape with walls (21).

Regarding claims 3, 9, and 10, Rausing includes a vacuum for drawing the film to make the enclosure.

8. Claims 1, 8, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Svec (US Patent No. 5,765,345).

Svec discloses a method of forming a package which includes heating a thin sheet of thermoformable film, clamping the edge of the film at spaced locations, and driving the platen where a resulting bag enclosure is formed. (See Figure 1.) The method can be used for medical items, such as blood collection tubes.

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Svec does not specifically state that the method is used for an aseptic enclosure for medical equipment.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the method as set forth in Svec for making an aseptic enclosure for medical equipment, because Svec talks about storing items such as blood collection tubes.

9. Claims 2 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rausing as applied to claim 1 above, and further in view of Repik et al. (US Patent No. 4,380,484).

Rausing does not disclose using an 'annular' clamp.

Repik shows use of an annular clamp (55).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use an annular clamp depending on the type of enclosure the artisan is trying to make. For example if the artisan wants to make a round enclosure, they would use an annular clamp. Thus, it is within the purview of one having ordinary skill in the art to use an annular clamp with the method Rausing if the object to be enclosed is circular.

10. Claims 2 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Svec as applied to claim 1 above, and further in view of Repik et al.

Svec does not disclose using an 'annular' clamp.

Repik shows use of an annular clamp (55).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use an annular clamp depending on the type of enclosure the artisan is trying to make. For example if the artisan wants to make a round enclosure, they would use an annular clamp. Thus, it is within the purview of one having ordinary skill in the art to use an annular clamp with the method Svec if the object to be enclosed is circular.

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11. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rausing as applied to claim 1 above.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use an elastic band on an adjacent open end of the enclosure, because using an elastic band in combination with something like a cover sheet to seal an item is well known in the art.

### ***Allowable Subject Matter***

12. Claims 5, 6, 11-13, and 19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

13. Claims 15-17 are allowed.

14. The following is an examiner's statement of reasons for allowance: Prior art fails to teach or suggest the use of a light sensitive audio chip for use in aseptic enclosure.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### ***Conclusion***

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sue A. Purvis whose telephone number is (571) 272-1236. The examiner can normally be reached on Monday through Friday 9am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher A. Fiorilla can be reached on (571) 272-1187. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Sue A. Purvis", with a long horizontal stroke extending to the right.

Sue A. Purvis  
Primary Examiner  
Art Unit 1734

SP  
September 24, 2004